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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/669,656	06/24/96	WOOD	J 70086

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EXAMINER	
ALLEN, M	
ART UNIT	**PAPER NUMBER**
1818	

DATE MAILED: 07/02/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/669,656	Akopian et al.
Examiner	**Group Art Unit**
Marianne P. Allen	1818

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-17* is/are pending in the application.

Of the above, claim(s) *1-7, 15, and 16* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *8, 11-14, and 17* is/are rejected.

☒ Claim(s) *9 and 10* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *8 and 10*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to sodium channel proteins, classified in class 530, subclass 350.

II. Claims 8-14 and 17, drawn to nucleic acids encoding sodium channel proteins and recombinant methods using the nucleic acids, classified in class 536, subclass 23.5.

III. Claim 15, drawn to a method of identifying modulators, classified in class 435, subclass 7.1.

IV. Claim 16, drawn to an antibody, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product could be isolated from natural sources or made synthetically.

Groups I and III are related as sodium channels and method of identifying modulators. The inventions can be shown to be distinct because the proteins can be used to make the antibody of group IV.

Groups I and IV are related as sodium channels and antibody. The inventions can be shown to be distinct because the sodium channel can be used in the method of group III rather than used to make the antibody of Group IV.

Groups II and III are related as nucleic acids encoding sodium channels and a method for identifying modulators to the encoded channel. Groups II and IV are related as nucleic acids encoding sodium channels and antibody to sodium channels. Groups III and IV are related as a method for identifying modulators and antibody. The inventions of each named pair can be shown to be distinct because they do not rely upon each other for their ultimate use and they require non-coextensive literature searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Liza D. Hohenschutz on 23 May 1997 a provisional election was made with traverse to prosecute the invention of Group II, claims 8-14 and 17. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-7 and 15-16 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

The disclosure is objected to because of the following informalities:

Applicant has failed to direct insertion of the substitute sequence listing submitted 10 December 1996 (Paper No. 9). Applicant must direct replacement of the original sequence listing in the specification with the corrected sequence listing.

Claim 12 contains a typographical error, "ganglias."

Appropriate correction is required.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The enablement of claims 12 requires availability of NCIMB deposit number 40744. This determination has been made because the claim specifically recites this deposit and the materials required to construct it have not been shown to be publicly known and freely available. Accordingly, it is deemed that a deposit of NCIMB deposit number 40744 should have been made in accordance with MPEP 2402. In order to certify that the deposit meets the criteria set forth in MPEP 2402, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number. Applicant is advised that the Patent Office accepts Budapest approved deposits, as long as assurance is provided that the deposited materials will be made irrevocably available with no restrictions upon issuance of a patent.

The specification does not appear to specifically identify what sequence is present in this deposit. (See pages 3 and 5.) That is, it does not appear to be disclosed whether SEQ ID NOS: 1, 3, 5, or 7 is the referenced insert.

Claims 8, 11, 13-14, and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NOS: 1, 3, 5, and 7 and degenerate sequences encoding the same proteins does not reasonably provide enablement for other sensory neuron sodium channel proteins which are insensitive to tetrodotoxin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The specification does not appear to specifically define the metes and bounds of "mammalian senory neuron sodium channel protein" nor the level of sensitivity required to meet the limitation "insensitive to tetrodotoxin." As such, the claims are clearly not limited to the specific proteins disclosed in the specification. It is noted that on page 2 the specification indicates that the SNS sodium channel is present in sensory neurons but not in glia, muscle, sympathetic, parasympathetic, enteric, or central nervous systems. Preferred locations are the dorsal root ganglia (DRG) or cranial ganglia. This is inconsistent as the cranial nerves are part of the central nervous system and the DRG is found in the spinal cord which is also part of the central nervous system. Similarly, parasympathetic system neurons are found in brain stem nuclei

associated with the cranial nerves. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe nor enable identification of any other sodium channel proteins meeting the functional limitations of the claims and it is deemed to constitute undue experimentation to determine them. The enablement of the claims can be viewed similarly to those in Ex parte Maizel, 27 USPQ2d 1662, 1665. The Board of Patent Appeals and Interferences held that claims drawn to DNA sequences encoding biologically equivalent proteins (i.e. DNA encoding proteins that do not have a defined amino acid sequence) are not enabled when the specification discloses a single specific DNA sequence known to the inventor having the biological limitations. The disclosure was held not to be commensurate in scope with the breadth of such claims because DNA sequences encoding biologically equivalent proteins covers any DNA sequence encoding a protein which achieves the stated biological result. The disclosure is not commensurate in scope with the breadth of the claims.

In addition, the specification fails to provide any written description of polynucleotides that hybridize to nucleic acids encoding the SNS sodium channel of SEQ ID NOS: 1, 3, 5, and 7 (see claim 8) or polynucleotides encoding other species of this SNS sodium channel (e.g. human). It is noted that the specification discloses only rat sequences and that Example 2 at page 23 is prophetic. The specification fails to provide a written description of the structure of the genomic DNA (i.e introns, exons) and any allelic or splice variants of the gene. Conception is a question of law and like conception of any chemical substance, the conception of a DNA sequence requires definition of the substance other than by its functional utility (i.e. SNS sodium channel). Since the

specification lacks a clear written description of a chemical structure of the allelic variants, hybridizing sequences, or other polynucleotides encoding SNS sodium channels, it is not enabled for these polynucleotides because it fails to enable the skilled artisan to envision the detailed chemical structure of the encompassed polynucleotides, as well as the method of obtaining them, and therefore conception is not achieved until reduction to practice has occurred (Fiers v. Revel, 25 USPQ2d 1601 (CAFC 1993)). One cannot enable what one cannot conceive.

Claims 8, 11, and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is incomplete in depending upon non-elected claims 1-7.

Claims 8, 13, and 14 use improper Markush language and/or are improperly multiply dependent in reciting "claims X-Y." A claim should refer to other claims in the alternative only, (e.g. any one of claims X-Y or of claim X, Y, or Z).

Claim 11 is confusing in reciting "to strand of claim 8." It is unclear if both strands or only the complementary strand is intended.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 13-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Sangameswaran et al.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because the concept of the hybridizing sequence in claim 11 does not appear to be contemplated in this document.

Sangameswaran et al. discloses nucleic acids encoding a tetrodotoxin resistant sodium channel from DRG. The channel is expressed in Xenopus oocytes. (See abstract and page 5953.) As evidenced by Genbank Accession No. U53833, the nucleic acid sequence of this channel is virtually identical to SEQ ID NOS: 1, 3, 5, and 7 of the instant application. Absent evidence to the contrary, the few differences may be attributed to allelic variation and/or sequencing errors. The sequence disclosed by Sangameswaran would hybridize to SEQ ID NO: 1.

Claims 9, 11, and 13-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Akopian et al. (Nature, 1996).

The inventorship of the instant application is Akopian and Wood. The authorship of the Nature reference is Akopian, Sivilotti, and Wood. Thus, the reference is by "other" within the meaning of the statute.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because the concept of the hybridizing sequence in claim 11 does not appear to be contemplated in this document. The priority document does not clearly demonstrate a correspondence between the sequences disclosed therein and the claimed SEQ ID NOS: 3, 5, and 7. SEQ ID NOS: 3, 5, and 7 do not appear to be contemplated in the priority document. As such, claim 9 is entitled to benefit of only the instant application's filing date.

Akopian et al. discloses nucleic acids encoding a tetrodotoxin resistant sodium channel from DRG. The channel is expressed in Xenopus oocytes. The amino acid sequence is provided. (See abstract and Figure 1.) Although not explicitly disclosed, the nucleic acid sequences of these channels would be inherently the same as SEQ ID NOS: 1, 3, 5, and/or 7 of the instant application, absent evidence to the contrary.

Claims 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gautron et al.

Gautron et al. discloses nucleic acids encoding a sodium channel from DRG that is presumed to have low sensitivity to tetrodotoxin. (See abstract, Figure 2, and page 7273, right column.) This nucleic acid would hybridize to SEQ ID NO: 1 under some hybridization conditions. (See claim 11.)

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Rogart et al. (PNAS, 1989).

Rogart et al. discloses nucleic acid sequences that would hybridize to SEQ ID NO: 1 under some hybridization conditions. (See Figure 3.)

It is noted that Akopian et al. (Nature, 1996) indicates that the nucleic acid sequences disclosed correspond to the tetrodotoxin resistant sodium channels in DRG disclosed by Roy et al. (1992). However, Roy et al. does not suggest cloning these channels.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached on (703) 308-4310. The most convenient FAX telephone number for this examiner is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800